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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,766	10/04/2006	William Arthur Spiers	MRH-001	1622

22832 7590 03/09/2009

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,766	SPIERS, WILLIAM ARTHUR	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070409*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The abstract of the disclosure is objected to because it is insufficiently detailed as to the actual novelty of the leukapheresis process and apparatus. Correction is required. See MPEP § 608.01(b).

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "system" is not a statutory class of invention.

3. Claims 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what constitutes a "system" as is recited in instant claims 30-34. It is not clear if Applicant is claiming, e.g., an apparatus or a method. To the extent that Applicant is claiming an apparatus, it is not clear how the claimed "system" is distinguished from the "Apparatus" as is recited in instant claim 35. To the extent that Applicant is claiming a method, the system claims are indefinite because they do not recite any positive process steps. Claim 36 is indefinite because it refers to "the leukapheresis device of claim 22"; however, claim 22 is drawn to a process, not a leukapheresis device. Claims 37-39 are indefinite because of the presence of the parenthetical phrases "(or obtained)" and "(or obtained by)". The significance of enclosing the phrases within parentheses is not clear, e.g., it is not clear if the parenthetical phrases are intended to constitute claim limitations and/or if the parenthetical phrases are intended to constitute alternatives to the "obtainable" limitations. This issue could be overcome, e.g., by re-writing the claims without the use of the parentheses.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 23, 26-29, and 37-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 10/561,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '766 application anticipate instant claims 21, 23, 26-29, and 37-40. Note that the '766 application claims producing leukocytes from an isolated blood sample (claim 26) using a closed or functionally closed leukapheresis system (see claim 7), does not claim returning the treated blood sample to the donor, and claims using the treated blood sample as a cryopreservation medium (claim 24). The '766 application claims iterative application of the process (claims 8, 28, and 29). Claims 44-47 of the '766 application anticipate the instant claims 37-40. Note that process limitations do not impart patentability to product-by-process claims where the product is otherwise taught by the applied art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

6. Claims 21, 26-29, and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/88099. The WO Patent Application '099 teaches a method of autologous transplantation of cells when the need or desire to do so arises, i.e. contingent autologous transplantation. A preferred cell type is a T-lymphocyte, which is a type of leukocyte, obtained from peripheral blood. Sampling can occur iteratively over a period of time for later autotransplantation. The blood from which the T-lymphocytes are to be removed need not be returned to the patient, i.e. is an isolated blood sample. In Example 1, where T-

lymphocytes are collected from peripheral blood by differential centrifugation on a density gradient, the blood sample is not returned to the donor. The collected cells can be rendered dormant, e.g., by cryopreservation, and then revitalized prior to transplantation. See, e.g., page 9, lines 12-20; page 15, lines 7-12; page 17, line 37 - page 18, line 7; page 19, line 20 - page 20, line 3; page 26, line 31 - page 27, line 33; page 29, lines 19-22; page 38, line 18 - page 39, line 20. The collected T-lymphocytes of the WO Patent Application '099 anticipate instant claims 37 and 38. Note also that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

7. Claims 22, 24, and 36 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 01/88099. Application of the WO Patent Application '099 is the same as in the above rejection of claims 21, 26-29, and 37-40. The WO Patent Application '099 teaches collecting T-lymphocytes from a peripheral blood sample by differential centrifugation on a density gradient, but does not teach such a step using an automated differential centrifugation device. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use an automated differential centrifugation device in the method of the WO Patent Application '099, because it is prima facie obvious to automate a manual activity. See MPEP 2144.04(III).

8. Claims 21, 23, 26-28, 30-35, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Der Heiden et al (U.S. Patent No. 5,879,318). Van Der Heiden et al teach a method for producing a leukocyte composition from umbilical cord blood using a closed sterile collection bag system which is assembled, filled, sterilized, and packaged at the manufacturer's place of business. After separation of the leukocyte composition from the erythrocyte and

plasma fractions of the umbilical cord blood, cryoprotectant is added to the leukocyte composition for cryopreservation. The leukocyte composition, which contains stem cells, can be used to form cell banks. The umbilical cord blood from which the leukocytes and erythrocytes has been removed is not returned to the donor, i.e. is an isolated blood sample. See, e.g., column 1, line 57 - column 2, line 8; column 2, lines 63-67; column 3, lines 54-62; column 5, lines 12-42; column 6, lines 15-19; and Figures 3 and 4. Van Der Heiden et al's apparatus also anticipates Applicant's system and apparatus, in which the needle 13 corresponds to Applicant's sampling means for collecting a blood sample from the individual; the collection bag 14 corresponds to Applicant's sample vessel in fluid communication with the sampling means; tube 20 and processing bag 23 correspond to Applicant's blind tubing set in fluid communication with the sample vessel, leukocyte collection vessel, and blood processing vessel; and processing bag 37 corresponds to Applicant's blood processing vessel and vessel for residual blood from which the leukocytes have been removed. See, e.g., Figures 3, 4, and 7; and column 5, lines 13-42 and 62-65.

9. Claim 22 and 36 are rejected under 35 U.S.C. 103(a) as being obvious over Van Der Heiden et al (U.S. Patent No. 5,879,318). Application of Van Der Heiden et al is the same as in the above rejection of claims 21, 23, 26-28, 30-35, 37, and 38. Van Der Heiden et al do not teach an automated apparatus for performing their leukocyte separation. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to automate the leukocyte separation apparatus of Van Der Heiden et al, because it is prima facie obvious to automate a manual activity. See MPEP 2144.04(III).

10. Claims 25, 39, and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Van Der Heiden et al (U.S. Patent No. 5,879,318) as applied against claims 21, 23, 26-28, 30-35, 37, and 38, and further in view of the WO Patent Application 01/88099. Van Der Heiden et al teach the use of stem cell-containing leukocyte compositions to form cell banks, but do not teach iterative application of their leukocyte separation to a series of blood samples from different donor individuals, and do not teach the use of the cryopreserved leukocyte compositions for autotransplantation, e.g., for contingent autologous transplantation. The WO Patent Application '099 teaches separating and storing cells, including stem cells and leukocytes, for purposes of autologous transplantation of cells when the need or desire to do so arises, i.e. contingent autologous transplantation. Sampling from a donor can occur iteratively over a period of time for later autotransplantation. See, e.g., page 9, lines 12-20; page 14, line 35 - page 15, line 12; and page 19, lines 20 37. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to perform the leukocyte separation of Van Der Heiden iteratively to a series of blood samples from different donor individuals, and to use the cryopreserved leukocyte compositions of Van Der Heiden et al for contingent autologous transplantation, because the WO Patent Application '099 teaches that these are known techniques for collecting and using leukocytes.

11. Claims 21-23, 25, and 30-38 are rejected under 35 U.S.C. 103(a) as being obvious over Judson et al (U.S. Patent No. 3,489,145). Judson et al teach a method and apparatus for separating white cells/leukocytes from donor blood. The apparatus is automated, can be closed, uses continuous flow centrifugation, comprises various tubes and pumps, and comprises a needle for removal of blood from the donor. See, e.g., column 5, lines 27-44 and 71-74; column 6, lines

59-64; column 7, lines 6-17; and Figures 1 and 18. Judson et al's method and apparatus are designed so that some components of the blood are continuously returned to the donor (see, e.g., the Abstract and column 5, lines 13-21 and 36-38), because if whole blood is entirely removed from the donor, then the amount and frequency of donation is limited to 500 cc every 60 days to allow for red blood cell replacement (see, e.g., column 3, line 68 - column 4, line 16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made in the method and apparatus of Judson et al to omit the return of any part of the donor blood to the donor with only the expected results that leukocytes still can be removed from the donor blood (i.e. lack of a return of any part of the donor blood to the donor does not affect the ability to remove leukocytes from the donor blood which is removed from the donor) albeit in smaller amounts (because of limitations on the amount and frequency of blood donation as explained by Judson et al). It is prima facie obvious to omit a method step or apparatus element when the result or function of the step or element is not desired. See MPEP 2144.04(II)(A).

12. Bosch et al (U.S. Patent Application Publication 2005/0173315) and Corbin, III et al (U.S. Patent Application Publication 2003/0146170) are cited as art of interest, being essentially duplicative of the references applied above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal

communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
March 9, 2009